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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/575,809
Filing Date: April 13, 2006
Appellant(s): AVRAMOFF ET AL.

D'vorah Graeser
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 23, 2010 appealing from the Office action mailed November 23, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 are rejected.

Claims 1 – 6, 8, 10 – 16, 18, 20, 21, 23 – 25 and 51 – 57 are pending but withdrawn.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 6,210,712	EDGREN	05-2001
WO 96/24375	DEPUI	08-1996
EP 1174136	LUNDBERG	01-2002
US 2002/0150618	NAPPER	10-2002
US 2003/0155153	DEPUI	10-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 26 – 32, 34, 36 – 40, 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (WO 96/24375; WO'375) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712).

WO'375 discloses an oral, enteric coated dosage form comprising an acid labile proton pump inhibitor useful in the treatment of disorders associated with *Heliobacter* infections (abstract). In examples 5 (beginning of p 28) and 12 (beginning on page 39), a multilayer dosage form comprising lansoprazole (in the free base form, not as a pharmaceutically acceptable salt) is prepared. The core contains a sugar sphere seed (neutral core) coated with lansoprazole, the cellulosic polymer hydroxypropyl methyl cellulose (HPMC) and water (aqueous solvent). No alkaline material is present in the core. The size of the core can vary between 0.1 – 2 mm (p 13, ln 13 – 14). The separating layer (subcoating layer of the instant claims) comprises the cellulosic polymer hydroxypropyl cellulose, the filler talc, magnesium stearate and the solvent water. An enteric coating layer comprising a methacrylic acid copolymer and the plasticizer triethyl citrate (a citric acid ester) is present in the dosage form. The active ingredient can be mixed with other ingredients such as binders, surfactants and fillers (p 13, ln 18 – 26). In example 18 (beginning on page 46), the surfactant sodium lauryl

sulfate and the filler anhydrous lactose are included in the same layer as the active benzimidazole ingredient (omeprazole).

WO'375 does not disclose the use of sodium stearate or a surfactant such as polysorbate 80 or sodium lauryl sulfate in the subcoating layer.

Lundberg et al. discloses similar trilayer (active ingredient core, intermediate layer and enteric layer) dosage form containing proton pump inhibitor compounds. In example 1 (beginning on p 9), a separating layer comprising talc (filler), sodium dodecyl sulfate (surfactant, also know as sodium lauryl sulfate), microcrystalline cellulose (cellulosic polymer) and magnesium stearate is added. These ingredients are mixed with granulated active ingredient and no solvent is present. No other pharmaceutically active substances are present in the dosage form. Disclosed pharmaceutically acceptable surfactants include non-ionic and ionic surfactants such as sodium lauryl sulfate or polysorbates (¶ [0032]).

Edgren et al. discloses that potassium stearate, magnesium stearate and sodium stearate as pharmaceutically acceptable lubricants (col 8, ln 6 – 10).

It would have been obvious to one of ordinary skill in the art to prepare a multi-layer dosage form as disclosed by WO'375 and to use sodium stearate and a surfactant such as polysorbate 80 or sodium lauryl sulfate in the subcoating layer as Lundberg teaches that such a composition is suitable for use a barrier layer between the substrate containing a proton pump inhibitor and the enteric coating layer. Claim 26, subitem (b) uses the transitional phrase "consisting essentially". Because of the use of the completely open transitional phrase "comprising" in the preamble and the absence of a

clear indication in the specification or claims, the transitional phrase "consisting essentially of" is still being interpreted as comprising (emphasis added, see MPEP 2111.03). The specification of the instant application teaches that this layer of the composition separates the enteric coating from the active agent contained in the substrate and prevents the ingredients in those two parts from interacting. This is the same purpose described by Depui and Lundberg for this layer of its compositions. The addition of other excipients to this layer does not change or “materially affect” the ability of the subcoating layer to separates the enteric coating from the active agent contained in the substrate and prevents the ingredients in those two parts from interacting.

WO ‘375 discloses that surfactants can be included in the dosage form and Lundberg discloses that polysorbate 80 or sodium lauryl sulfate are surfactants suitable for inclusion in the subcoating layer of trilayer, benzimidazole proton pump inhibitor containing dosage forms. Selection of excipients for a dosage form is part of routine formulation and optimization by one of ordinary skill in the art, based on the cost, availability of various excipients and the interactions which may occur between the different excipients and the other ingredients in both the subcoating layer and adjacent layers of the oral lansoprazole dosage form.

The composition of WO’375 contains both a benzimidazole proton pump inhibitor such as lansoprazole and an antibiotic while the compositions disclosed by Lundberg only contain a benzimidazole proton pump inhibitor. Thus, Lundberg teaches the presence of an antibacterial compound in a proton pump dosage form is not required. In

maintenance therapy where control of stomach acidity by the proton pump inhibitor is desired but the bacterial infection has been treated, a dosage form with only lansoprazole would be appropriate to reduce the chances of an antibacterial resistant strain of bacteria developing.

The person of ordinary skill in the art would have been motivated to use sodium stearate and reasonably would have expected success because WO'375 teaches that magnesium stearate can be used in subcoating layer and Edgren et al. discloses that magnesium stearate and sodium stearate are functionally equivalent, as they are both lubricants.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui WO'375, Lundberg and Edgren et al. further in view of Napper et al. (US 2002/0150618).

WO'375, Lundberg and Edgren et al. discloses a lansoprazole dosage form with an active substrate center that does not contain an alkaline substance; a subcoating layer containing sodium stearate, a cellulosic polymer such as HPMC, a filler, polysorbate 80 or sodium lauryl sulfate as the surfactant and a solvent; and an enteric coating.

Depui WO'375 discloses the use of anhydrous lactose as a filler material but not the use of lactose monohydrate.

Napper et al. discloses that either lactose monohydrate or anhydrous lactose are suitable directly compressible pharmaceutically acceptable excipients (¶ [0016]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use lactose monohydrate in the lansoprazole containing pharmaceutical composition taught by Depui WO'375, Lundberg and Edgren et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Napper et al. teaches that lactose monohydrate and anhydrous lactose are functionally equivalent as excipients and one of ordinary skill would select the appropriate material based on availability of the different hydrate forms and any moisture demands of the pharmaceutical formulation process.

Claims 26 – 32, 34, 36, 38 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 2002/0155153, Depui '153) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712).

In example 4 (¶ [0109]) of Depui '153, enteric coated tablets of lansoprazole are prepared. These dosage forms are administered one to several times a day to treat gastrointestinal side effects caused by NSAIDs (non-steroidal anti-inflammatory drugs; ¶ [0087]). The core consists of non-pareil cores coated with water, the surfactant sodium lauryl sulfate, lansoprazole and the cellulosic polymer HPMC. A separating (subcoating) layer comprised of water and ethanol as solvents, the filler talc, the surfactant polyethylene glycol 6000 (PEG 6000) and the cellulosic polymer HPMC is applied. Then an enteric coating of hydroxypropoly methylcellulose phthalate, the plasticizers acetyltributyl citrate and cetanol (cetyl alcohol) is applied to the pellets. The separating

layer may serve as a diffusion barrier and pH-buffering zone (¶ [0062]). To strengthen the buffering capacity of this layer, substance such as the inorganic salts generally used as antacids (for example, aluminum or calcium hydroxide, carbonate or silicate; or magnesium oxide, carbonate or silicate), weak inorganic acids such as citric acid or suitable organic bases such as the basic amino acids are added (¶ [0062]). The enteric coating layer can be comprised of a number of materials, including methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate phthalate and cellulose acetate trimellitate (¶ [0064]). The enteric layer may also contain pharmaceutically acceptable plasticizers such as citric acid esters, phthalic acid esters, cetyl alcohol and polysorbates (¶ [0065]).

Depui '153 does not disclose a lansoprazole preparation in which sodium stearate is present in the separating layer, or the inclusion of sodium stearate, polysorbate 80 and/or sodium lauryl sulfate in the subcoating layer.

Lundberg et al. discloses similar trilayer (active ingredient core, intermediate layer and enteric layer) dosage form containing proton pump inhibitor compounds. In example 1 (beginning on p 9), a separating layer comprising talc (filler), sodium dodecyl sulfate (surfactant), microcrystalline cellulose (cellulosic polymer) and magnesium stearate is added. These ingredients are mixed with granulated active ingredient and no solvent is present. No other pharmaceutically active substances are present in the dosage form. Disclosed pharmaceutically acceptable surfactants include non-ionic and ionic surfactants such as sodium lauryl sulfate or polysorbates (¶ [0032]).

Edgren et al. discloses that potassium stearate, magnesium stearate and sodium stearate are functionally equivalent (col 8, ln 6 – 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer lansoprazole oral dosage for administration as taught by US'153 and to include a polysorbate or sodium lauryl sulfate surfactant in the subcoating layer, taught as suitable for inclusion in the separating layer by Lundberg. It also would be obvious to use a lubricant in the subcoating layer, such as the magnesium stearate used in the subcoating layer of the trilayer proton pump inhibitor dosage forms of Lundberg or sodium stearate. The examples of Depui '153 contain magnesium stearate, which is taught as functionally equivalent to sodium stearate by Edgren et al. Substitution of one compound known in the art to be functionally equivalent with another such compound is *prima facie* obvious.

Claim 26, subitem (b) uses the transitional phrase "consisting essentially". Because of the use of the completely open transitional phrase "comprising" in the preamble and the absence of a clear indication in the specification or claims, the transitional phrase "consisting essentially of" is still being interpreted as comprising (emphasis added, see MPEP 2111.03). The specification of the instant application teaches that this layer of the composition separates the enteric coating from the active agent contained in the substrate and prevents the ingredients in those two parts from interacting. This is the same purpose described by Depui and Lundberg for this layer of its compositions. The addition of other excipients to this layer does not change or "materially affect" the ability of the subcoating layer to separates the enteric coating

from the active agent contained in the substrate and prevents the ingredients in those two parts from interacting.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui US'153, Lundberg and Edgren et al. further in view of Depui et al. (WO 96/24375) and Napper et al. (US 2002/0150618).

Depui '153, Lundberg and Napper et al. teaches a lansoprazole dosage form with an active substrate center that does not contain an alkaline substance; a subcoating layer containing sodium stearate, a cellulosic polymer such as HPMC, a filler, polysorbate 80 or sodium lauryl sulfate as the surfactant and a solvent; and an enteric coating.

None of the references discloses the use of lactose as a filler material in the layer with the lansoprazole.

WO '375 discloses that anhydrous lactose can be present in the core material (substrate) of multi-layered benzimidazole proton pump inhibitor dosage (e.g., example 18 on p 46).

Napper et al. discloses that either lactose monohydrate or anhydrous lactose are suitable directly compressible pharmaceutically acceptable excipients (¶ [0016]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use lactose monohydrate in the lansoprazole containing pharmaceutical composition taught by Depui '153, Lundberg and Edgren et al. The person of ordinary skill in the art would have been motivated to make those

modifications and reasonably would have expected success because Depui '375 teaches that anhydrous lactose can included in the substrate layer and Napper et al. teaches that lactose monohydrate and anhydrous lactose are functionally equivalent as excipients and one of ordinary skill would select the appropriate material based on availability of the different hydrate forms and any moisture demands of the pharmaceutical formulation process.

Claims 39 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Appellant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from claim 27, which already requires the presence of the inorganic, alkaline agent sodium stearate in the subcoating layer. Claims 39 and 40 require that the subcoating contain an organic basic salt (claim 39) such as sodium stearate (claim 40) but this ingredient has already been required by claim 27. Therefore, claims 39 and 40 do not further limit claim 27.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. Appellant does not have support for formulations in which lansoprazole is the "sole active ingredient". This limitation is not explicitly recite din the specification and there is neither implicit nor inherent support for such a limitation. The various formulations prepared contain lansoprazole but also contain other ingredients which are active ingredients. The subcoating layer of the dosage form contains an alkaline agent, which is an active substance in that it alters or controls the pH of the formulation. The examples prepared also contain other pharmaceutically active ingredients. The formulation in example 5 contains the surface active agent sodium lauryl sulfate, which is used in the treatment of varicose veins. The lactose present in the substrate and subcoating layer of example 1 is pharmaceutically active as a nutrient which provides carbohydrates. Therefore, Appellant does not have support for administering a therapeutically effective amount of lansoprazole as sole active ingredient.

(10) Response to Argument

Claims 26 – 32, 34, 36 – 40, 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (WO 96/24375; WO'375) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712).

Appellants traverse this rejection on the grounds that the characterizing feature of the present invention is that the substrate is devoid of an alkaline agent while an alkaline agent [sodium stearate] is provided in the separating layer. Magneisum stearate is taught by Depui WO'375 as an example of an additive such as a plasticizer, colorant,

pigment, filler, anti-tacking agent or antistatic agent and is not included in the list of possible alkaline agents given elsewhere in the specification. The amount of magnesium stearate used, such as less than 2% in Example 1, is clearly not sufficient to act as anything other than lubricant and could not act as an alkalizing agent.

These arguments are unpersuasive. The patentability of the instant composition is based on the ingredients which are present in the formulation and not on the function ascribed to them by either the applied prior art or the instant application. Both the formulations of Depui WO'375 and the instant application do not contain any alkaline agent in the substrate and contains a stearate compound in the separating layer. In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., the amount of stearate ingredient in the subcoating layer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant also argues that the properties of magnesium stearate are such that it cannot be defined as an alkaline agent while sodium stearate can and therefore sodium stearate and magnesium stearate cannot be considered functionally equivalent as alkalinizing agents. The functional equivalence of sodium and magnesium stearate taught by Edgren is in the context of their use as lubricating agents and not as alkalinizing agents. It would not have been obvious in view of the teachings of the equivalence of the stearates as lubricating agents to use sodium stearate instead of

magnesium stearate for the entirely different purpose. These arguments are unpersuasive. As highlighted by Appellant, Depui WO'375 teaches magnesium stearate not as an alkalinizing agent but as a lubricant and the functional equivalence of magnesium stearate and sodium stearate as lubricants is appreciated by Edgren. In light of this, one of ordinary skill in the art would substitute sodium stearate for magnesium stearate as the lubricant in the composition of Depui WO'375. That this is not the purpose for which Appellant chose this ingredient is not germane as the composition arrived at contains the same ingredients as the composition of the instant claims.

Appellants also paste a section for the November 23, 2009 Office Action in which the Examiner talks about sodium stearate and magnesium stearate having slightly different properties not being germane as the stated purpose of the two stearate compounds in the cited prior art was to function as an alkalinizing agent. This was confusing to Appellant as the Examiner is maintaining that these very different stearate compounds which are taken as functionally equivalent for one purpose may also be considered functionally equivalent for an entirely different purpose, even though the Examiner acknowledges that the compounds would not be expected to have exactly the same properties. These arguments are unpersuasive. The Examiner did not and is not commenting on the functional equivalence of magnesium stearate and sodium stearate as alkalinizing agents. As discussed above, Depui WO'374 teaches magnesium stearate as a lubricant and Edgren teaches both sodium and magnesium stearate are lubricants, establishing the functional equivalence of these two ingredients for the

purpose taught by the primary reference. That functional equivalence renders the substitution of the magnesium stearate in the lansoprazole formulations of Depui WO'375 with sodium stearate obvious, resulting in the composition of the rejected claims.

Appellants also argue that Depui '375 comprises omeprazole and not lansoprazole and the two are not interchangeable. The magnesium salt of omeprazole is significantly more stable than lansoprazole and thus does not require alkalizing agents for stabilization. These arguments are unpersuasive. While example 1 (p 21) utilizes omeprazole, Example 5 (p 28) uses lansoprazole. Depui '375 discloses that omeprazole and lansoprazole are examples of proton pump inhibitor (p 7 – 8) and therefore are interchangeable in the proton pump inhibitor dosage forms which are disclosed. The dosage forms of Depui '375 teach the presence of a stearate for lubrication purposes and that is sufficient motivation for inclusion of a stearate, regardless of the stability of the particular proton pump inhibitor selected and the need for alkalizing agents in the formulation.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui WO'375, Lundberg and Edgren et al. further in view of Napper et al. (US 2002/0150618).

Appellant argues that the primary rejection doesn't teach a formulation in which the substrate is free of alkalizing agents while an alkalizing agent [sodium stearate] is present in the separating layer. The Examiner finds this argument unpersuasive,

because as discussed above, the primary rejection does teach a formulation in which the substrate is free of alkalizing agent and the separating (subcoating) layer contains sodium stearate.

Claims 26 – 32, 34, 36, 38 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. (US 2002/0155153) in view of Lundberg (EP 1174136) and Edgren et al. (US 6,210,712).

Appellant argues this rejection along similar lines as discussed above in that magnesium stearate is not an alkalizing agent and the Examiner has offered no evidence that magnesium and sodium stearate are functionally equivalent as alkalinizing agents. Appellants have actually provided evidence that these two agents were not functionally equivalent. These arguments are unpersuasive. Just as in the rejections based upon the Depui WO'375 reference, the Depui '153 reference teaches the presence of magnesium stearate in the subcoating layer as a lubricant and Edgren teaches the functional equivalence as lubricants of sodium stearate and magnesium stearate. The substitution of magnesium stearate with the functionally equivalent for the purpose taught by the primary references results in a composition having the same compositions as the compositions of the instant claims.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Depui US'153, Lundberg and Edgren et al. further in view of Depui et al. (WO 96/24375) and Napper et al. (US 2002/0150618).

Appellant argues that the primary rejection doesn't teach a formulation in which the substrate is free of alkalizing agents while an alkalizing agent [sodium stearate] is present in the separating layer. The Examiner finds this argument unpersuasive, because as discussed above, the primary rejection does teach a formulation in which the substrate is free of alkalizing agent and the separating (subcoating) layer contains sodium stearate.

Claims 39 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Appellant traverses this objection on the grounds that claim 39 requires an additional ingredient be present but acknowledges that claim 40 is an improper dependent claim. This argument is unpersuasive. Claim 27, from which claim 39 depends, requires the presence of sodium stearate, which as shown by claim 40, is a particular species within the genus of "organic basic salt" recited in claim 39. There is no language in claim 39 indicating that this is an additional ingredient but is only further defining the element "alkaline agent" which has already been defined in claim 27 to be sodium stearate.

It is also noted that objections are petitionable matters and are not appealable. The Board will not hear or decide issues pertaining to objections and formal matters which are not properly before the Board. These formal matters should not be combined in appeals to the Board. (see MPEP 706.01) Therefore, this matter should not have been raised in the Appeal Brief.

Claims 26 – 32, 34, 36 – 42, 44, 46, 47, 49, 50, 58 and 59 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Appellant traverses this rejection on the grounds that all formulations relate to lansoprazole and throughout the application is described as being a "formulation for lansoprazole" and MPEP 608.01(o) states that "applicant is not limited to the nomenclature used in the application as filed" and the limitation "sole pharmaceutically active ingredient" in relation to lansoprazole is both implicitly and inherently supported in the present application.

These arguments are unpersuasive. Appellants are correct in the implicit and/or inherent support in the specification as filed can provide written description. "Lansoprazole formulations" implicitly requires the presence of lansoprazole, but does not provide any information regarding the absence or presence of additional active ingredients in the preparation. Appellants have also not rebutted the argument set forth by the Examiner as to other ingredients in the formulations that are pharmaceutically active.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nissa M Westerberg/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612